REMARKS

Claims 1, 3-12, 14, 15 and 28-29 are presently pending in the application.

Claim 1 has been amended to recite that the electrode base member is in direct contact with an electrically conducting layer, which is supported in the specification at least in Figs. 2-7. No new matter has been added by this amendment, and entry is respectfully requested.

In the present Office Action, the Examiner has rejected claims 1, 3-5, 14, 15 and 28-29 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,935,158 of Holmstrom et al. ("Holmstrom") in view of U.S. Patent No. 4,784,161 of Skalsky et al. ("Skalsky"), U.S. Patent No. 6,844,023 of Schulman et al. ("Schulman"), U.S. Patent No. 5,683,443 of Munshi et al. ("Munshi") and a technical article by Gibbs et al. ("Gibbs"). Claims 6, 7, 10 and 12 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Holmstrom, Skalsky, Schulman, Munshi and Gibbs and further in view of U.S. Patent No. 6,799,076 of Gelb et al. ("Gelb"). Additionally, claims 8 and 9 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Holmstrom, Skalsky, Schulman, Munshi, Gibbs and Gelb in view of U.S. Patent No. 4,440,178 of Bussard et al. ("Bussard"). Finally, the Examiner has rejected claim 11 under 35 U.S.C. § 103(a) as being unpatentable over Holmstrom, Skalsky, Schulman, Munshi, Gibbs and Gelb in view of U.S. Patent No. 5,609,611 of Bolz. Applicants respectfully traverse these rejections and the arguments in support thereof as follows, and respectfully request reconsideration and withdrawal of the rejections.

Rejection Under § 103(a) Based on Holmstrom in view of Schulman, Skalsky, Munshi and Gibbs

Regarding claims 1, 3-5, 14, 15, 28 and 29, the Examiner contends that in Figs. 1A-1B, Holmstrom teaches element 40, a stimulation electrode comprising an electrically conducting electrode base member formed of at least one metal selected from the group consisting of platinum, wherein an electrode base member is at least partially coated with an electrically conducting layer comprising a material which may be titanium nitride. The Examiner acknowledges that Holmstrom does not teach an electrode base member which is partially covered with an electrically insulating ceramic layer and is formed of an oxide and/or an oxynitride of a metal, such as aluminum, and has a thickness of about 1 nm to about 20 μm, or that an iridium portion of the alloy is 21 wt % and a platinum portion of the alloy is ≥ about 100 ppm as claimed.

However, Skalsky allegedly discloses an electrode base member which is partially covered with an electrically insulating ceramic layer and is formed of an oxide and/or an oxynitride of a metal which may be aluminum, and Schulman allegedly teaches a ceramic layer having a thickness of about 1 nm to about 20 μm. Further, the Examiner argues that Mushi teaches a concentration of an iridium portion of the alloy to be 21 wt %. Finally, Gibbs allegedly teaches a platinum portion of an alloy to be ≥ 100 ppm to provide an electrode having high pacing impedance, low current drain, low sensing impedance for enhanced sensing and to provide lower long-term pacing thresholds, to coat and protect microminiature components and devices that are intended to be implanted in living tissue, to maintain electrical leakage of such components within acceptable limits, to significantly reduce the polarization loss and improve the efficiency of the energy transfer through the tissue, and to enhance capacitance and reduce conductance.

Accordingly, the Examiner argues that it would have been obvious to have modified the invention of Holmstrom to include an electrode base member which is partially covered with an electrically insulating ceramic layer and is formed of an oxide and/or an oxynitride of a metal such as aluminum having the claimed thickness and concentrations of platinum and iridium as taught by Skalsky, Schulman, Munshi and Gibbs to improve and enhance electrode performance. Applicants respectfully traverse this rejection as follows.

The stimulation electrode according to the presently claimed invention contains a metal base material which is partially covered with an electrically insulating ceramic layer formed of a particular metal oxide or oxynitride and is also partially covered with <u>and in direct contact with</u> an electrically conducting layer. The metal oxide or oxynitride is specifically selected for its electrically insulating properties, and may be formed, for example, by depositing a metallic layer and performing thermal, electrochemical or chemical oxidation, or oxynitriding. As explained in paragraph [0009] of the present application, it has been found that ceramic layer thicknesses of about 1 nm to about 20 μm are particularly advantageous. It is important to the presently claimed invention that the electrically conducting layer be applied directly to and in direct contact with the electrode, as shown in Figs 3-7, for example. Such an electrically conducting layer may comprise titanium nitride, niobium nitride, tantalum nitride, zirconium nitride, aluminum nitride, silicon nitride, iridium oxide and/or specific alloys of platinum and iridium.

In Figs. 1A and 1B and col. 3, lines 1-5, Holmstrom teaches an electrically conductive core 40 which is covered by an electrically conducting layer 60. However, the conducting layer

of Holmstrom is not in direct contact with the electrically conductive core, but rather is applied to the piezoelectric material 50 which covers the core. The conducting layer does not come into direct contact with the core as in the presently claimed invention.

As acknowledged by the Examiner, Holmstrom does not teach or suggest partially covering the core with an electrically insulating ceramic layer, but contends that such an element is taught by Skalsky. As explained below, there would have been no motivation to combine Holmstrom with Skalsky. Further, Applicants respectfully traverse the Examiner's understanding of Skalsky and her assertion that an electrically insulating ceramic layer is taught by Skalsky.

Skalsky teaches that an electrically conducting body (electrode) is inserted in a ceramic base member (porous substrate). Skalsky teaches in col. 5, lines 27-30 that the substrate 60 has a central passage 62 for containing the shaft 54 of the electrode 56. Accordingly, the substrate of Skalsky could not be classified as a layer as claimed. Rather, the porous substrate of Skalsky would necessarily have had a thickness of considerably over 20 μm in order to function as described, that is, to be thick enough to define a central passage for receiving an electrode shaft. Skalsky does not teach or suggest the claimed thickness, and such a thickness could not be utilized in the Skalsky invention because it would render the porous substrate unfit for its intended purpose. Specifically, reducing the thickness of the porous substrate of Skalsky to the claimed thickness (or utilizing the thickness of Schulman, as propsed by the Examiner) would reduce its stability, without which it would not be possible to define a central passage for introduction of the shaft of the electrode (see, for example, Figs. 2 and 5 of Skalsky). Accordingly, Skalsky does not teach or suggest the claimed thickness and it would not have been obvious to modify the porous substrate of Skalsky to the thickness of the claimed ceramic layer. Thus, even the proposed combination of Holmstrom and Skalsky would not contain an electrically insulating ceramic layer as claimed.

As previously explained, Holmstrom does not teach or suggest a base member which is at least partially coated with and in direct contact with an electrically conducting layer and there would have been no motivation to modify the design of Holmstrom, which requires an intermediate piezoelectric material, in order to arrive at the claimed invention. Further, none of the secondary references would suggest such a modification to the Holmstrom device. For example, as previously explained, Skalsky teaches an electrode inserted into a ceramic substrate, and Schulman merely teaches ceramic layers having a particular thickness.

The Examiner argues that Mushi teaches a concentration of an iridium portion of the platinum/iridium alloy to be 21 weight %. To the contrary, Munshi teaches implantable stimulation electrodes which are coated with metal oxides. In the section of Munshi relied upon by the Examiner (col. 24, lines 42-45), Munshi describes an electrode coated with a mixture of ruthenium oxide, iridium oxide, and tantalum oxide in a 50/25/25 ratio. Even if such a mixture were to reduce polarization loss and improve the efficiency of energy transfer between two stimulation electrodes, as asserted by the Examiner, there is no suggestion that an iridium/platinum alloy coating containing at least 21% iridium, as claimed (and not a mixture of metal oxides), would provide similar results. That is, Munshi discloses an iridium oxide, but not an iridium portion of the alloy, and is silent about an iridium content in a platinum/iridium alloy as claimed.

Finally, the Examiner argues that Gibbs teaches a platinum portion of an alloy to be at least 100 ppm. Applicants respectfully traverse the Examiner's understanding of Gibbs. Gibbs describes platinum electrodes and their interaction with alkali halide crystals. However, Gibbs does not refer to an alloy of platinum and iridium at all, and thus does not give any hint that the platinum portion of the alloy is greater than about 100 ppm. Gibbs also does not teach an electrically conducting layer. Therefore, Applicants respectfully traverse the Examiner's interpretation of Gibbs and the rationale for combining Gibbs with the other primary and secondary references.

For all of these reasons, even the proposed combination of Holmstrom, Skalsky, Schulman, Munshi, and Gibbs were proper, which Applicants submit it is not, the proposed combination would not teach or suggest all of the claimed elements. Accordingly, reconsideration and withdrawal of the § 103(a) rejection are respectfully requested.

Rejection Under § 103(a) Based on Holmstrom, Skalsky, Schulman, Munshi, Gibbs and Gelb

Regarding claims 6 and 12, the Examiner acknowledges that none of the previously cited references discloses an electrically conducting layer that is at least partially covered with at least one oxidation protection layer on it side facing away from an electrode base member or a thickness of about 500 nm to about 5 μm. However, the Examiner contends that Gelb discloses such an electrically conducting layer formed of titanium nitride to achieve lower polarization. Therefore, the Examiner concludes that it would have been obvious to modify the invention of

Holmstrom, Skalsky, Schulman, Munshi and Gibbs to include the electrically conducting layer taught by Gelb to achieve lower polarization.

Regarding claims 7 and 10, the Examiner acknowledges that a ceramic layer arranged on at least one oxidation protection layer and an oxidation protection layer formed of platinum and/or iridium are not taught. However, Skalsky allegedly discloses such a ceramic layer to provide an electrode having high pacing impedance, low current drain, low sensing impedance for enhanced sensing and to provide lower long-term pacing thresholds. Therefore, the Examiner concludes that it would have been obvious to one having ordinary skill in the art at the time of the invention to have modified the combination of Holmstrom, Schulman, Munshi, Gibbs, and Gelb to include the Skalsky ceramic layer to enhance and improve electrode performance. Applicants respectfully traverse this rejection as follows.

As previously explained, the proposed combination of cited references is not proper and such a combination would not teach or suggest all of the claimed elements, such as an electrode which is partially covered with and in direct contact with a specific electrically conductive layer or a specific electrically insulating layer. Gelb would not cure the deficiencies with these references. Rather, Gelb teaches a coated electrode having a substrate covered by a first porous layer and a second layer containing iridium. The first layer may contain titanium nitride. However, Gelb does not teach or suggest that the titanium nitride layer has the claimed thickness, or the specific claimed concentration of iridium and platinum in the platinum/iridium alloy. Further, Gelb teaches a titanium nitride porous layer on an electrode. Even if such a titanium nitride layer could be equated with the claimed oxidation protection layer, Gelb does not teach that such a titanium nitride layer covers an electrically conducting layer as claimed.

Accordingly, even the proposed combination with Gelb would not teach or suggest all of the claimed elements, and reconsideration and withdrawal of the § 103(a) rejection are respectfully requested.

Rejection Under § 103(a) Based on Holmstrom, Skalsky, Schulman, Munshi, Gibbs, Gelb and Bussard

Regarding claims 8 and 9, the Examiner acknowledges that even the proposed combination of references does not teach a ceramic layer arranged adjacent to an electrically conducting layer of titanium nitride and at least one oxidation protection layer on an electrode base member or a ceramic layer arranged adjacent to at least one oxidation protection layer on an

electrically conducting layer of titanium nitride. However, Bussard allegedly teaches these elements to provide an electrode which has a low stimulus threshold and reaches the chronic stimulus threshold very rapidly. Accordingly, the Examiner concludes that it would have been obvious to have modified the invention of Holmstrom/Skalsky/Schulman/Munshi/Gibbs/Gelb to include these elements, as taught by Bussard, to provide an electrode which has a low stimulus threshold and reaches the chronic stimulus threshold very rapidly. Applicants respectfully traverse this rejection as follows.

As previously explained, the proposed combination of Holmstrom, Skalsky, Schulman, Munshi, Gibbs, and Gelb would not result in the presently claimed invention because there would have been no motivation to make the proposed combination nor would the proposed combination teach or suggest all of the claimed elements. Bussard teaches a porous electrode containing a sintered member made of electrically conductive particles which may be metal, a metal alloy, a metal compound of tantalum, titanium, niobium, and/or zirconium or a cobalt-chromium-based alloy (col. 1, lines 59-62). A portion of the surface is covered with a material of lower electrical conductivity than the particles, and another portion is coated with a metal. However, Applicants do not understand the Examiner's conclusion that Bussard teaches an electrode, a ceramic layer, an electrically conducting layer, and an oxidation protection layer since Bussard only teaches <u>two</u> materials which are applied to an electrode.

Accordingly, even the proposed combination with Bussard would not teach or suggest all of the claimed elements, and reconsideration and withdrawal of the § 103(a) rejection are respectfully requested.

<u>Rejection Under § 103(a) Based on Holmstrom, Skalsky, Schulman, Munshi, Gibbs and Gelb in view of Bolz</u>

Finally, regarding claim 11, the Examiner acknowledges that the Holmstrom/Skalsky/Schulman/Munshi/Gibbbs/Gelb combination does not disclose an oxidation protection layer formed of at least one oxide, carbide, nitride, and/or polymer which reduces the impedance of the electrode base member coated with the electrically conducting layer of titanium nitride, or at most increases the impedance to a value which is smaller than the impedance of the uncoated electrode base member. However, Bolz allegedly discloses such an oxidation protection layer which provides the claimed property to an electrode base member. Therefore, the Examiner concludes that it would have been obvious to one skilled in the art at the

time of the invention to have modified the Holmstron/Skalsky/Schulman/Munshi/Gibbs/Gelb invention to include the oxidation protection layer of Bolz to provide the desired impedance reduction or increase, as taught by Bolz, for picking up heart signals for which the low temperature frequency range is particularly important, especially in the region where the signals are weak. Applicants respectfully traverse this rejection as follows.

As previously explained, the proposed combination of Holmstrom, Skalsky, Schulman, Munshi, Gibbs, and Gelb is not proper and would not teach or suggest the claimed elements. Bolz teaches a stimulation electrode containing a porous surface coating made of an inert material, which may be a nitride, carbide, carbonitride or pure element or alloy of gold, silver, titanium, iridium, platinum or carbon (col. 9, lines 22-23 and col. 10, lines 49-53). However, Bolz does not teach or suggest an electrode, a ceramic layer, an electrically conducting layer, <u>and</u> an oxidation protection layer. Accordingly, even the proposed combination with Bolz would not teach or suggest all of the claimed elements, and reconsideration and withdrawal of the § 103(a) rejection are respectfully requested.

In view of the preceding Amendments and Remarks, it is respectfully submitted that the pending claims are patentably distinct from the prior art of record and in condition for allowance. A Notice of Allowance is respectfully requested.

Respectfully submitted,

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